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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,424	12/20/2001	Thomas W. Leonard	8789-24	3706

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/029,424	LEONARD ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32,34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on June 29, 2005 have been received and entered into the application.

Action Summary

The rejection of claim 35 under 35 U.S.C. 102(b) as being anticipated by Huber et al. (U.S.Patent No. 5,908,638) is hereby expressly withdrawn in view of Applicants' cancellation of the claim.

The rejection of claim 32 under 35 U.S.C. 103(a) as being unpatentable over Huber et al. (U.S.Patent No. 5,908,638) in view of Chesnut et al. (Metabolism Clinical and Experimental, 1983) is being maintained for the reasons stated in the previous Office Action.

The rejection of claim 34 under 35 U.S.C. 103(a) as being unpatentable over Huber et al. (U.S.Patent No. 5,908,638) in view of Chesnut et al. (Metabolism Clinical and Experimental, 1983) is being maintained for the reasons stated in the previous Office Action.

Response to Arguments

Applicants' arguments filed on June 29, 2005 have been fully considered but they are not persuasive. Applicants argue Huber et al. does not teach or suggest Claims 32 and 34 of the present application because Huber et al. fails to teach or suggest a composition consisting essentially of a mixture of estrogenic compounds wherein said mixture "comprises salts of conjugated estrone, conjugated equilin, conjugated $\Delta^{8,9}$-

dehydroestrone, conjugated l7a-estradiol, conjugated l7b-dihydroequilin, conjugated 17a-dihyroequilin, conjugated l7p-estradiol, conjugated equilenin, conjugated 17a-dihydroequilenin, and conjugated l7p-dihydroequilenin" and " therapeutically effective amount of a non-aromatizing androgenic compound". This is not persuasive because Huber clearly teach the composition of conjugated estrogen and progesterone as shown in Example 1 and any of conjugated estrogens listed in table 1, column 9 can be employed in the composition. Huber teaches the therapeutic effective amount of conjugated estrogen(0.9mg, see example 1) which is within Applicants' therapeutic effective amounts disclosed in the specification page 3, [0017]. Applicants further argue the present application illustrates data in an overiectomized mouse model that demonstrates that estrogen/androgen therapy with an aromatizing androgen has a more detrimental effect on the uterus as evidenced by increased weight of the uterus than treatment of a non-aromatizing estrogen/androgen combination and Chest et al. fails to teach or suggest a composition consisting essentially of a mixture of estrogenic compounds set forth in the claims. This is not persuasive because instant claims are drawn to "composition" claims not "method" claims. Therefore, it would have been obvious to one of ordinary skill in the art to combine two references (Huber et al. and Chest et al.) for treatment of post-memopausal disorder in woman because stanozolol is effective for the treatment of postmemopausal osteoporotic women as taught by Chesnut et al. and because Huber et al. teach postmenopausal women have decrease in estrogen level causing osteoporosis. One would have been motivated to combine conjugated estrogen and stanozolol in a single composition in order to conveniently

treat women suffering from postmeopausal disorder, osteoporosis. The motivation for combining the components flows from their individually known common utility (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). Thus, the claims fail to patentably distingusih over the state of the art as represented by the cited references.

In view of the above Office Action of March 30, 2005 is deemed proper and asserted with full force and effect and repeated herein to obviate applicants' claims.

Claim Rejections - 35 USC § 103

Claims 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huber et al. (U.S.Patent No. 5,908,638) in view of Chesnut et al. (Metabolism Clinical and Experimental, 1983).

Huber et al. teach composition comprising conjugated estrogen composition including (estrone, equilin, 17-alpha-estradiol, 17-alpha-dihydroequilin, 17-beta-dihydroequilin, 17-beta-estradiol, 17-alpha-dihydroequilenin, 17-beta-dihydroequilenin, equilenin, and Δ8,9 dehydroestrone useful for the treatment of per-menopausal, menopausal and post-menopausal disorder in women. (abstract, column 9, TABLE 1). Humber et al. teach postmenopausal women frequently experience a large variety of disorders related to the decrease of estrogen levels in the body such as osteoporosis. (column 1, lines 30-36).

Huber et al. do not teach the non-aromatizing androgenic compound set forth in claim 32 in a single composition with the conjugated estrogens.

Chesnut et al. teach therapeutic efficacy of stanozolol in postmenopausal osteoporotic women and long-term use of stanozolol may increase the net total bone mass above pretreatment levels. (abstract).

It would have been obvious to one of ordinary skill in the art to combine conjugated estrogen composition taught by Huber et al. with stanozolol in a single composition because the composition comprising conjugated estrogen taught by Huber et al. is useful for the treatment of post-menopausal disorder in woman and because stanozolol is effective for the treatment of postmenopausal osteoporotic women as taught by Chesnut et al. One would have been motivated to make such a modification in order to achieve at least an additive effect in treatment of postmenopausal disorder, osteoporosis, in a single convenient formulation.

Claims 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huber et al. (U.S.Patent No. 5,908,638) in view of Chesnut et al. (Metabolism Clinical and Experimental, 1983).

Huber et al. teach composition comprising conjugated estrogen composition including (estrone, equilin, 17-alpha-estradiol, 17-alpha-dihydroequilin, 17-beta-dihydroequilin, 17-beta-estradiol, 17-alpha-dihydroequilenin, 17-beta-dihydroequilenin, equilenin, and Δ8,9 dehydroestrone in combination with progestogen useful for the treatment of per-menopausal, menopausal and post-menopausal disorder in women.

(abstract, column 9, TABLE 1). Humber et al. teach postmenopausal women frequently experience a large variety of disorders related to the decrease of estrogen levels in the body such as osteoporosis. (column 1, lines 30-36).

Huber et al. do not teach the non-aromatizing androgenic compound set forth in claims 34 in a single composition with the conjugated estrogens and a progestogen.

Chesnut et al. teach therapeutic efficacy of stanozolol in postmenopausal osteoporotic women and long-term use of stanozolol may increase the net total bone mass above pretreatment levels. (abstract).

It would have been obvious to one of ordinary skill in the art to combine conjugated estrogen and progestogen composition taught by Huber et al. with stanozolol in a single composition because the composition comprising conjugated estrogen taught by Huber et al. is useful for the treatment of post-menopausal disorder in woman and because stanozolol is effective for the treatment of postmenopausal osteoporotic women as taught by Chesnut et al. One would have been motivated to make such a modification in order to achieve at least an additive effect in treatment of postmenopausal disorder, osteoporosis, in a single convenient formulation.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
August 29, 2005